IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation, and THE CURATORS OF THE UNIVERSITY OF MISSOURI, a public corporation and body politic of the State of Missouri,	)	
Plaintiffs,	)	C.A. No. 07-551-GMS
v.	)	
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendant.	)	

PLAINTIFF'S MOTION TO DISMISS

Santarus, Inc. ("Santarus") hereby moves to: (1) dismiss the First, Second and Third Counterclaims of Defendant Par Pharmaceutical, Inc. ("Par") with respect to U.S. Patent 5,840,737 (the "'737 patent"), or in the alternative, stay the litigation relating to issues of infringement, validity or enforceability of the '737 patent pending the outcome of the reissue proceeding currently ongoing before the Patent Office relating to the '737 patent.

I. Nature and Stage of These Proceedings

In this suit for patent infringement, Santarus, Inc. (referred to as "Plaintiff") sued Par Pharmaceutical, Inc. ("Par") for infringement of four patents: United States Patent Nos. 6,699,885 ("the '885 patent"); 6,489,346 ("the '346 patent"); 6,645,988 ("the '988 patent"); and 6,780,882 ("the '882 patent") (collectively the "Patents-in-Suit"). The Complaint (hereinafter "Comp.") did not contain any mention of United States Patent No. 5,840,737 ("the '737 patent"). *See* Comp. ¶ 12 (not listing the '737 among the "Patents-in-Suit"). On January 30, 2008, Par filed an amended answer and counterclaims (hereinafter "Ans.") seeking a declaration from the Court that both the Patents-in-Suit and the '737 patent were (1) invalid; (2) not infringed; and (3)

not enforceable as a result of inequitable conduct. Ans. ¶¶ 12, 21, 26, 93.[1] Plaintiff filed an answer to the counterclaims on February 22, 2008, along with this motion.

II. Statement of Facts

The University of Missouri is the owner of record of the '885, '346, '988, '882, and '737 patents. *See* Declaration of Joseph A. Mahoney ("Mahoney Decl.") at ¶ 2 (filed herewith). Santarus is the exclusive licensee of these patents. *Id.* at ¶ 3. These patents are listed in the United States Food and Drug Administration's (the "FDA's") *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, in support of Santarus' Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg ("Zegerid") products. Zegerid is the first and only immediate-release oral proton pump inhibitor approved by the FDA.

This action was commenced after Par submitted Abbreviated New Drug Application ("ANDA") No. 79-182 to the FDA. Comp. ¶ 14. Par seeks approval to market generic versions of Zegerid powder in 20 mg and 40 mg doses before the expiration of the patents listed in the Orange Book. *Id*. Plaintiff received a letter from Par, dated November 13, 2007, notifying them that the ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that, in Par's opinion, the patents listed in the Orange Book are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of a 20 mg generic Zegerid powder. Comp. ¶ 15. Plaintiff later

[1] At the status conference on February 11, 2008, the Court directed that the present case be consolidated with No. 07-551-GMS, which was filed several months earlier and involves only the '346, '988, and '885 patents. That earlier case involves a proposed generic to the capsule, rather than powder, version of Santarus' Zegerid product.

received a letter from Par, dated December 6, 2007, notifying them that its ANDA also includes a Paragraph IV certification for a 40 mg generic Zegerid powder. Comp. ¶ 16.

Plaintiff commenced this action on December 20, 2007 asserting that Par's proposed generic products would infringe the '885, '346, '988, and '882 patents. Plaintiff, however, did not assert the '737 patent. Instead, the '737 patent was placed into reissue proceedings before the United States Patent and Trademark Office (the "PTO") on December 20, 2007. Mahoney Decl. at ¶ 4.[2]

III. Summary of Argument

1. There is no present case or controversy over the '737 patent as Plaintiff did not assert the '737 patent and instead placed it into reissue proceedings that will yield a new patent with different claims. Accordingly, the Court does not have jurisdiction over Par's declaratory judgment claims related to the '737 patent.

2. Even if jurisdiction were proper, however, the reissue proceedings concerning the '737 patent also will result in a new patent with presently uncertain claim scope. Thus, the Court should decline to exercise jurisdiction over Par's declaratory judgment claims related to the current incarnation of the '737 patent.

3. Finally, even if the Court were to find and exercise jurisdiction, it should stay Par's declaratory judgment claims related to the '737 patent until after the reissue is completed as there is no prejudice to Par at this early stage of the proceedings and the claim scope and strength will be clarified upon reissue of the '737 patent.

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[2] The reissue process has just begun and the University has not yet received any communication from the Patent Office with respect to the reissue application. Mahoney Decl. at ¶ 5.

IV. Argument

Plaintiff moves pursuant to Federal Rule of Civil Procedure 12(b)(1) to dismiss Par's First, Second, and Third Counterclaims with respect to the '737 patent for lack of subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Plaintiff did not assert the '737 patent in this litigation and instead placed it into reissue proceedings. Therefore, there is no justiciable case or controversy that would support declaratory judgment jurisdiction over Par's counterclaims with respect to the '737 patent. As a result, these counterclaims should be dismissed.

A. Legal Standards

The Supreme Court recently summarized the requirements for subject matter jurisdiction under the Declaratory Judgment Act: "'the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *MedImmune Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). The Federal Circuit has confirmed that a declaratory judgment plaintiff in an ANDA litigation must demonstrate that, under "all the circumstances," a justiciable Article III "controversy" exists. *Teva Pharms. U.S.A., Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007).

To have standing to bring a claim, a plaintiff must demonstrate a harm that is: "(a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quotations, citations omitted). The injury cannot be speculative, and must be redressable by a decision in the plaintiff's favor. *Id.* at 561. A controversy must also be ripe for judicial review: the defendant's actions must "have harmed, are harming, or about the harm the plaintiff." *Teva*, 482 F. 3d at 1337. A controversy is

ripe if "postponing a decision would work a substantial hardship on the challenging party." *Id.* Finally, the constitutional requirement for a "controversy" prohibits courts from giving advisory opinions. Courts may only decide actual controversies, and cannot "'give opinions upon moot questions or abstract propositions.'" *Id.* (quoting *Local No. 8-6, Oil, Chem. & Atomic Workers Int'l Union v. Missouri*, 361 U.S. 363, 367 (1960)). In particular, "the Supreme Court maintains the necessity of avoiding issuing advisory opinions based upon hypothetical facts." *Id.* (citing *Elec. Bond & Share Co. v. Sec. & Exch. Comm'n*, 303 U.S. 419 (1938)).

B. The Court Lacks Subject Matter Jurisdiction over Par's Counterclaims Directed to the '737 Patent

Par's counterclaims related to the '737 patent do not meet the requirements for a justiciable controversy under Article III, and therefore this Court lacks jurisdiction under the Declaratory Judgment Act to hear them. First, the fact that the claims of the reissued version of the '737 patent are, as yet, unknown makes any future harm to Par purely hypothetical. As a result, the issues raised in Par's counterclaims concerning the '737 patent are not ripe and any proceeding would be a prohibited advisory opinion. Second, because Plaintiff did not assert the '737 patent against Par, but instead put it into reissue, there is no substantial controversy between the parties.

1. The Claims of a Pending Reissue Patent Are Hypothetical Making a Declaratory Judgment Claim Unripe.

The threat that the '737 patent will, at some point in the future, emerge from the reissue process is insufficient to support declaratory judgment jurisdiction for Par's counterclaims. This Court recently considered an analogous situation, wherein a declaratory judgment counterclaim was brought against a patent in reissue, and found that "the question of whether a new patent will ever be reissued is speculative, purely hypothetical." *Pfizer Inc. v.*

Ranbaxy Labs. Ltd., __ F. Supp. 2d __, 2007 WL 4226417, at *4 (D. Del. Nov. 29, 2007).[3] Because the harm from a patent in reissue was purely "speculative," the *Pfizer* Court held that there was there was no Article III standing to bring the counterclaim. The Court also held that the declaratory judgment counterclaims for non-infringement, invalidity, and unenforceability were not ripe for adjudication until the patent was actually reissued. *Id*.

Applying the reasoning in *Pfizer* to this case, the pending reissue proceedings render Par's declaratory judgment claims against the '737 patent not ripe for adjudication. The hypothetical harm of the pending '737 patent reissue is not enough to give Par standing to bring a declaratory judgment counterclaim. *Id*. Moreover, the exercise of declaratory judgment jurisdiction over the pending reissue patent "would result in nothing more than an advisory opinion regarding the enforceability of a yet to be reissued patent, a result wholly inconsistent with the most basic precepts of jurisdictional jurisprudence." *Id*.

2. There Is Currently No Substantial Controversy Between the Parties

There is no substantial controversy between the parties with respect to the '737 patent. The current version of the '737 patent was not asserted by the Plaintiff against Par. Instead it was placed into reissue. At the conclusion of that process, the '737 patent automatically will be surrendered and replaced with a new reissue patent. 35 U.S.C. § 251; United States Patent and Trademark Office, The Manual of Patent Examining Procedure ("MPEP") § 1416 (Aug. 2007). Thus, given the fact that the '737 patent effectively has been returned to prosecution, there is no present case or controversy. *Compare Teva*, 482 F.3d at

[3] *Pfizer* differs from this case in that the branded pharmaceutical maker granted a covenant not to sue on the pre-reissue of its patent. Judge Farnan, however, made a point to analyze both the effect of that covenant and the effect of the reissue process.

1341 (subject matter jurisdiction based on threat of post-ANDA suit under § 271(a)) *with Pfizer*, 2007 WL 4226417, at *4 (no subject matter jurisdiction despite hypothetical threat of future litigation against ANDA filer after reissue). Any harm to Par from a reissue application that may issue sometime in the future, with claims as yet unknown, is too uncertain and hypothetical to support declaratory judgment jurisdiction. Par's counterclaims concerning the '737 patent should be dismissed.

C. Even if Jurisdiction Were Proper, The Court Should, In Its Discretion, Decline To Exercise Any Such Jurisdiction

Even if the Court were to find that it had subject matter jurisdiction over the '737 patent, the Court should, in its discretion, decline to exercise that jurisdiction. The Declaratory Judgment act gives district courts "substantial discretion" when "deciding whether to declare the rights of litigants." *Wilton v. Seven Falls Co*., 515 U.S. 277, 286 (1995). Although the Declaratory Judgment Act allows a court to declare the rights of any interested party, it does not require the court to do so. *MedImmune*, 127 S. Ct. at 776. The Act "confers a discretion on the courts rather than an absolute right upon the litigant." *Wilton*, 515 U.S. at 287.

Litigating issues related to the '737 patent at this point in time will be wasteful of both the Court's and the parties' resources. What the claims of the '737 patent will be following reissue is, at this time, "speculative [and] purely hypothetical." *Pfizer*, 2007 WL 4225417, at *4. Once the reissue is finished, the current version of the '737 patent will disappear, and a new patent with different claims will take its place. Par's declaratory judgment counterclaim asks this Court and the parties to devote time and resources to conducting a *Markman* hearing on claims that will change, taking evidence of infringement on claims that will change and considering the validity of claims that will change. Moreover, any judgment resulting from this exercise – in either party's favor – likely will be mooted by grant of the reissue patent with new

claims. The Court should decline Par's invitation to engage in such wasteful, duplicative and ultimately futile litigation.[4]

D. Alternatively, The Court Should Stay Any Counterclaim Related To The '737 Patent Pending The Results Of The Reissue

For the reasons discussed above, if the Court finds it does have jurisdiction over Par's counterclaims and decides to exercise that jurisdiction, it should stay the proceedings until the '737 patent has reissued. When deciding whether to grant a stay in the face of a pending reissue, courts consider three factors: "'(i) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (ii) whether a stay will simplify the issues in question and trial of the case; and (iii) whether discovery is complete and whether a trial date has been set.'" *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, 2007 WL 2892707, at *4 (D. Del. Sept. 30, 2007) (quoting *Xerox Corp. v. 3 Com Corp*., 69 F. Supp. 2d 404, 406 (W.D.N.Y.1999)).

Each of the three factors weighs in favor of a stay. First, Par will suffer no prejudice as a result of a stay since staying the counterclaims against the '737 patent does not affect Par's ability to litigate its other counterclaims and defenses. In particular, Par itself has conceded that the '737 patent does not need to be part of its suit in order to litigate its dubious claims of infectious unenforceability: Par brought declaratory judgment counterclaims seeking the same relief from this Court in a related case (No. 07-551-GMS) without asserting any claims

[4] Par likely will point out that it also has alleged that purported inequitable conduct during prosecution of the '737 patent renders unenforceable all of Plaintiff's later, separately filed and prosecuted patents. Although Plaintiff believes Par's "infectious" unenforceability claim is without merit, Par's own pleadings make clear that even Par does not believe a declaratory judgment claim as to the '737 patent is necessary to resolve these allegations. In the first of these consolidated actions, No. 07-551-GMS, Par made substantially the same infectious unenforceability allegations, asserting that the '346, '988 and '885 patents are unenforceable not because of any alleged inequitable conduct in their prosecution, but because of purported misconduct in the prosecution of the '737. Par nevertheless made no attempt to assert any declaratory judgment claim against the '737 at that time.

against the '737 patent. Second, the reissue process will clarify the core issues in the counterclaims. The reissue will clarify the issue of non-infringement by defining the claims of the '737 patent, and will clarify the issue of invalidity by indicating the strength of those claims. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 961 (Fed. Cir. 1986) (examiner's decision on reissue is proof of validity of patent). Finally, this case is at the very earliest stage of the proceedings. Given the potential for wasteful and unnecessary expenditure of resources by the Court and the parties, Par's counterclaims related to the '737 patent should be stayed pending the outcome of the reissue process.

V. Conclusion

Par asks the Court to declare the '737 patent invalid, not infringed, and unenforceable. Since the '737 patent has not been asserted against Par and is currently undergoing reissue, Par has not suffered any harm and thus does not have standing to bring these counterclaims. Despite lacking standing, Par still asks the Court to take jurisdiction and issue an advisory opinion regarding counterclaims that are not yet ripe. This is not allowed under either the Declaratory Judgment Act or the Constitution. Moreover, litigating issues related to the '737 patent while it is in reissue will waste the time and resources of the parties and the Court. For the reasons stated above, Par's First, Second, and Third Counterclaims with respect to the '737 patent should either be dismissed by the Court for lack of subject matter jurisdiction under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, be dismissed by the Court in an exercise of its substantial discretion in deciding whether to declare the rights of litigants, or stayed by the Court pending the outcome of the ongoing reissue proceeding.

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February 22, 2008
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CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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